UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

RALICA ZAMFIROVA, RACHAEL MAHER, JASMIN AMARO, MARINA GOMEZ, ANGELE NELSON, REBECCA TORRES, CAROLYN GILL, MARY JO BARNES, TERESA FAUGHNAN, JENNIFER MALTESE, LISA BRADY and KIMBERLY MEFFERT, individually and on behalf of others similarly situated, Plaintiffs, v. AMAG PHARMACEUTICALS, INC., Defendant.	Civil Action No. 220-CV-00512-JMV-SCM Honorable John M. Vazquez, U.S.D.J. Honorable Steven C. Mannion, U.S.M.J.

BRIEF IN SUPPORT OF DEFENDANT AMAG PHARMACEUTICALS, INC.'S MOTION TO DISMISS THE CONSOLIDATED AMENDED COMPLAINT

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AMAG Pharmaceuticals, Inc. ("AMAG") submits this Brief in Support of its Motion to Dismiss Plaintiffs' Consolidated Amended Complaint (the "Complaint") pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure ("FRCP").

PRELIMINARY STATEMENT

In this consolidated consumer class action, Plaintiffs improperly seek to challenge the United States Food and Drug Administration's ("FDA") determination that the prescription drug Makena (hydroxyprogesterone caproate injection), a progestin treatment indicated to reduce the risk of preterm birth, is safe and effective for its indicated use. Notwithstanding the FDA's approval of Makena in 2011, Plaintiffs argue that various statements on the Makena website, which essentially track the FDA-approved package insert, misrepresent Makena's efficacy and therefore are "misleading" under certain state consumer protection laws. Plaintiffs' claims directly challenge the FDA's original efficacy determination when it approved the drug and its authority over pharmaceutical product labeling, and therefore are preempted by federal law and barred by the doctrine of primary jurisdiction.

Plaintiffs' state-law claims also fail for a host of other reasons. Plaintiffs' New York, New Jersey and California consumer protection claims are barred by statutory or precedential "safe harbors" that make clear that a plaintiff cannot maintain a consumer protection claim related to the sale of a highly regulated prescription drug product like Makena that was marketed in accordance with FDA requirements. Additionally, although couched as consumer protection claims, the thrust of the Complaint is that AMAG failed to warn patients of alleged concerns regarding Makena's efficacy. But such claims clearly are barred by each relevant state's learned intermediary doctrine. Plaintiffs further fail to plausibly allege essential elements of their consumer protection claims – including that the statements at issue are likely to mislead a reasonable consumer, that Plaintiffs suffered an ascertainable loss, or that the statements caused

any purported injury – much less with the heightened particularity required by Rule 9(b), which applies to all but one of Plaintiffs' claims. Indeed, Plaintiffs do not even allege that they saw the purportedly misleading statements prior to purchasing Makena. Finally, Plaintiffs' unjust enrichment claims fail because: (1) they are duplicative of their deficient consumer protection claims; and (2) they do not allege that they conferred any benefit directly on AMAG.

STATEMENT OF FACTS

A. The FDA and the Accelerated Approval Process

The Food, Drug, and Cosmetic Act of 1938 ("FDCA") is a federal law that governs – among other things – the testing, manufacture, promotion and sale of prescription drugs and, together with its implementing regulations, represents a comprehensive regulatory regime for the approval and post-approval monitoring of prescription drug products like Makena. Under that regime, the FDA is vested with exclusive authority to approve prescription drug products before they may be sold in the United States. *See* 21 U.S.C. § 355(a)-(d) (2018). The FDA approves a prescription drug if it determines that the product is safe and effective for its indicated use. *Id.* Under the FDCA, the FDA must "protect the public against danger to human life arising from use of unsafe and ineffective drugs by assuring that before any drug is marketed it will have been carefully reviewed by FDA experts." *Premo Pharm. Labs., Inc. v. United States*, 629 F.2d 795, 802 (2d Cir. 1980); *see also In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 751 F.3d 150, 153 (3d Cir. 2014) ("Under the FDCA, a manufacturer must seek approval from the [FDA] to market a new drug and, in doing so, must first file a New Drug Application . . . and then prove the drug's safety and efficacy and propose accurate and adequate labeling.").

The FDCA's regulatory scheme for prescription drug products is extremely rigorous. To obtain approval to market a new drug, a manufacturer must submit to the FDA a detailed new drug application ("NDA") containing "full reports of investigations which have been made to

show whether or not such drug is safe for use and whether such drug is effective in use." 21 U.S.C. § 355(b)(1). The manufacturer must demonstrate to the FDA that the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling," and also must prove the drug's effectiveness by "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling." *Id.* § 355(d). Drug manufacturers also must submit proposed labeling, with annotations, to be used with the drug. *Id.* § 355(b)(1); 21 C.F.R. § 314.50(c)(2)(i) (2016). The FDA's premarket approval of a NDA includes the agency's approval of the exact text in the final product labeling. *See* 21 U.S.C. § 355(d); 21 C.F.R. § 314.105(b).

The FDCA and its implementing regulations contemplate an "accelerated approval" pathway for certain new drugs – but that process is no less rigorous. Specifically, under 21 U.S.C. § 356(c) and the implementing regulations at 21 C.F.R. Part 314 Subpart H, the FDA may grant marketing approval for a new drug based on adequate and well-controlled clinical trials establishing that the drug has an effect on a surrogate endpoint that is reasonably likely – based on epidemiologic, therapeutic, pathophysiologic, or other evidence – to predict clinical benefit. *See* 21 U.S.C. § 356(c)(1)(A) (2016); 21 C.F.R. § 314.510. Accelerated approval is reserved for drugs that, like Makena, are intended to treat a serious or life-threatening condition and that provide meaningful therapeutic benefit to patients over existing treatments, such as the ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy. *See* 21 C.F.R. § 314.500. Importantly, to obtain accelerated approval, a

drug still must meet the FDA's regulatory standard of "substantial evidence" of effectiveness for the intended use.[1]

Once a drug is approved under the FDA's accelerated approval regulations, the agency generally requires the sponsor of the drug to conduct a post-approval clinical study to verify and further describe the drug's clinical benefit. *See* 21 C.F.R. § 314.510. If the post-approval confirmatory study does not verify the product's clinical benefit, the FDA has the authority to initiate proceedings to withdraw the accelerated approval of the drug. *Id*. § 314.530.

B. Makena and Defendant AMAG

In February 2011, the FDA determined, pursuant to the accelerated approval process, that Makena was safe and effective for its indicated use and approved Makena "to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth." (Ex. A, at 2; *see also* Compl. ¶¶ 29, 34).[2] Makena's FDA-approved package insert states:

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[1] *See FDA Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products*, 11 (May 1998), https://www.fda.gov/media/71655/download; *FDA Briefing Document, NDA 021945, Bone, Reproductive, and Urologic Drugs Advisory Committee Meeting*, 17 (Oct. 29, 2019), https://www.fda.gov/media/132003/download. The Court may take judicial notice of FDA guidance and consider it in deciding a motion to dismiss. *See Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc.*, 118 F. Supp. 3d 646, 655 n.7 (D.N.J. 2015) ("In deciding the pending motion to dismiss, the Court may take judicial notice of public records [or documents] of the FDA relating to the aripiprazole products at issue in this litigation.") (quotation omitted); *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 60 (2d Cir. 2016) (taking judicial notice of publicly available FDA "Guidance for Industry").

[2] A copy of Makena's FDA-approved labeling is attached as Exhibit A (pagination added for the Court's convenience), and is also available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021945s012lbl.pdf (last visited June 8, 2020). The Court may take judicial notice of Makena's labeling and consider it for purposes of this motion. *See Becker v. Smith & Nephew, Inc.*, Civ. No. 15-2538 (WHW) (CLW), 2015 WL 4647982, at *2 (D.N.J. Aug. 5, 2015) (taking judicial notice of information on FDA's website); *Gagnon v. Alkermes PLC*, 368 F. Supp. 3d 750, 762 (S.D.N.Y. 2019) ("Courts have taken judicial notice of the fact of disclosure of the contents of FDA labels, which can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.") (quotation omitted).

> Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity. Limitation of use: While there are many risk factors for preterm birth, safety and efficacy of Makena has been demonstrated only in women with a prior spontaneous preterm birth. **It is not intended for use in women with multiple gestations or other risk factors for preterm birth.**

(Ex. A, at 2). The labeling further describes the results of a multicenter, randomized, double-blind, placebo-controlled clinical trial that studied the effectiveness of Makena for the reduction of the risk of spontaneous preterm birth (the "Meis trial"):

> Compared to controls, treatment with Makena reduced the proportion of women who delivered preterm at < 37 weeks. The proportions of women delivering at < 35 and < 32 weeks also were lower among women treated with Makena.

(Ex. A, at 13). Although the Complaint highlights certain purported concerns regarding the Meis trial (Compl. ¶¶ 31-34), [3] the FDA addressed those concerns prior to approving the Makena, and characterized the trial's results as "compelling." (Ex. B, at 21).[4] Indeed, the FDA "determined that [the trial] was adequate, well-controlled and very persuasive and concluded that this single trial provided substantial evidence of an effect on a surrogate endpoint (effectiveness for reduction in the risk of recurrent preterm birth)." (*Id.* at 11).

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[3] AMAG disputes many of Plaintiffs' factual contentions, but acknowledges that, solely for purposes of deciding this motion, the Court must accept as true all well-pled allegations of fact. The Court need not, however, accept as true conclusory allegations or factual claims that are contradicted by properly considered documentary evidence. *See Wireless Media Innovations, LLC v. Maher Terminals, LLC*, 100 F. Supp. 3d 405, 407 (D.N.J. 2015) (citing *Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008)).

[4] A copy of the FDA Briefing Document, NDA 021945, from the Bone, Reproductive, and Urologic Drugs Advisory Committee Meeting referenced in Paragraph 32 of Complaint is attached as Exhibit B, and also is available at https://www.fda.gov/media/132003/download. The Court may take judicial notice of FDA documents for purposes of this motion. *See Otsuka*, 118 F. Supp. 3d at 660 n.7; *Becker*, 2015 WL 4647982, at *2.

Defendant AMAG acquired Makena in 2014. (Compl. ¶ 27). AMAG then marketed the prescription drug according to its FDA-approved indication and labeling. (*Id.* at ¶ 72). Specifically, as Plaintiffs alleged in each of the original complaints in this consolidated action, "Makena was and is marketed as an effective hormonal medication that reduces the risks for pregnant mothers of giving birth before term." (*E.g.*, ECF No. 1 at ¶ 37).

Prior to Makena's approval, in accordance with the requirements of the FDA's accelerated approval process, the original sponsor of the Makena NDA[5] initiated a confirmatory clinical trial, entitled "Progestin's Role in Optimizing Neonatal Gestation" (the "PROLONG trial"), to further evaluate Makena in patients with a history of prior spontaneous singleton preterm delivery. (Compl. at ¶¶ 58-60). In March 2019, AMAG announced "topline" results from the PROLONG trial. (*Id.* at ¶¶ 59-60 & n.37). The PROLONG trial results do not confirm the efficacy results of the Meis trial, but also do not invalidate those results – two randomized, well-controlled clinical trials performed in two different patient populations yielded disparate results. As AMAG explained:

> While PROLONG failed to confirm [Makena's] efficacy, it does not invalidate the results and conclusions from the Meis study. PROLONG, although designed to replicate the Meis study, evaluated a markedly different, international patient population with significantly lower background rates of preterm birth risk with more than 75 percent of subjects being enrolled from outside of the U.S. This lower risk patient population was reflective of the reluctance of U.S. physicians to enroll high-risk patients in a placebo-controlled study rather than prescribe [Makena]. As a consequence, the rate of recurrent preterm birth was considerably lower than expected, which resulted in PROLONG being underpowered. This unexpectedly lower rate of preterm birth, driven by ex-U.S. enrollment, raises uncertainty about the applicability of PROLONG to the higher risk U.S. population.

[5] AMAG acquired the rights to Makena from Lumara Health in 2014, several years after Makena was approved by the FDA. Lumara's predecessor had previously acquired those rights from the original sponsor, Hologic, Inc. (Compl. ¶¶ 23-27).

> Importantly, a favorable maternal and fetal safety profile of [Makena] was reaffirmed in PROLONG.
>
> Following the release of the PROLONG data, both the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine issued statements, which support the use of [Makena] in appropriate patients.

(Ex. C, at 2).[6] The import of the results of the PROLONG trial to the labeling and marketing of Makena is a matter squarely within the jurisdiction of the FDA.

C. Plaintiffs and Their Claims[7]

Plaintiffs allege that they were prescribed and purchased Makena at some point during the time period from January 1, 2011 to the present. (Compl. ¶¶ 2-13). Four of the twelve named Plaintiffs allege that they gave birth preterm, despite having taken Makena. Specifically, Plaintiff Teresa Faughnan, a New York resident, alleges that she gave birth to one child preterm at 36 weeks, and Plaintiff Jennifer Maltese, also a New York resident, alleges that she gave birth to four children preterm, two at 35 weeks, one at 34 weeks and one at 32 weeks. (*Id.* at ¶¶ 10-11). Plaintiff Mary Jo Barnes, a Missouri resident, alleges that while she was taking Makena, her child was born preterm at 24 weeks. (*Id.* at ¶ 9). Plaintiff Carolyn Gill, a Kansas resident, alleges that, while she was taking Makena, her child was born preterm at 37 weeks. (*Id.* at ¶ 8). Importantly, the approved indication for Makena is to ***reduce*** the risk of preterm birth (Ex. A, at 2); Makena is not approved or marketed to prevent preterm birth. None of these four Plaintiffs

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[6] The Complaint cites AMAG's press release, *AMAG Files Response to Citizen Petition*, AMAG Pharmaceuticals (January 21, 2020), https://www.amagpharma.com/news/amag-files-response-to-citizen-petition/, a copy of which is attached as Exhibit C (pagination added for the Court's convenience). (Compl. ¶ 69 n.44). The Court may consider the press release because it is incorporated by reference in the Complaint. *See Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006).

[7] Several of the Plaintiffs filed their original complaints in various jurisdictions and the parties jointly sought transfer and consolidation of each of those actions in this district. Pursuant to the Court's order dated March 19, 2020, Plaintiffs filed a Consolidated Amended Complaint on April 2, 2020. Plaintiffs purport to represent six state-wide classes (from New Jersey, New York, California, Kansas, Missouri and Wisconsin) of all purchasers of Makena for personal, family or household purposes during various time periods. (Compl. ¶ 78).

allege that Makena failed to reduce their risk of preterm birth, or whether they would have given birth earlier or later if they had not taken Makena. The remaining eight Plaintiffs, from New Jersey, California and Wisconsin, allege that they purchased Makena (*Id.* at ¶¶ 2-7, 12-13), but they do not even allege that they gave birth preterm.

Plaintiffs assert claims for violation of state consumer protection laws and unjust enrichment, based on allegations that certain statements on the Makena website and in AMAG's patient education brochure misrepresent the drug's effectiveness at preventing preterm births. Specifically, Plaintiffs identify the following statements, which they claim relate to Makena's efficacy, as the bases for their claims:

a. "Makena helps you get closer to term."

b. "Makena . . . is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past."

c. "Makena gives moms an extra layer of support."[8]

d. "[R]eceiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy."

e. "[L]ooking back, Makena gave me hope that I had a better chance of delivering Olivia full term."[9]

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[8] This statement precedes a hyperlink to Makena Care Connection® Support, AMAG's patient assistance program for Makena. *See Reducing Risk with Makena Auto-Injector*, Makena, https://makena.com/reducing-preterm-birth-risk-with-makena/ (last visited June 8, 2020). The hyperlink transfers viewers to a webpage describing the program's services. *See Makena Care Connection® Support*, Makena, https://makena.com/makena-care-connection-support/ (last visited June 8, 2020). The Complaint does not allege any facts suggesting that there is anything misleading about AMAG's statements relating to its patient assistance programs.

[9] This statement comes from a patient testimonial video. *See Watch Kate's Story*, Makena, https://makena.com/reducing-preterm-birth-risk-with-makena/#true-3 (last visited June 8, 2020). The video is prefaced with a clear disclaimer regarding Makena's efficacy, a copy of which is attached as Exhibit D: "Your experience with Makena may vary. The patient shown in this video is not a healthcare professional or medical expert. For medical questions, please contact

f. "Makena . . . helps give bab[ies] more time to develop."

(Compl. ¶¶ 72-74; 88, 95, 106, 116, 123, 132, 141). Plaintiffs do not, however, allege that any of them ever viewed any of the statements in question before purchasing Makena.[10]

STANDARD OF REVIEW

The standards governing a motion to dismiss are well known to the Court. First, while a court is obligated to accept all factual allegations within the complaint as true, this principle "is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). As such, because a court is "not bound to accept as true a legal conclusion couched as a factual allegation," "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Additionally, the Court need not accept as true allegations that are contradicted by documentary evidence subject to judicial notice, *see Gupta v. Wipro Ltd.*, 749 F. App'x 94, 97 (3d Cir. 2018), such as Makena's FDA-approved labeling.

Second, "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Iqbal*, 556 U.S. at 679 (quoting *Twombly*, 550 U.S. at 556). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' . . . A claim has facial plausibility when the Plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). The plausibility standard "asks for more than a sheer possibility that a defendant has acted

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your healthcare provider." *Id.*; *see Fink v. Time Warner Cable*, 714 F.3d 739, 742 (2d Cir. 2013) (stating that "the presence of a disclaimer or similar clarifying language may defeat a claim of deception.").

[10] Nor do Plaintiffs allege that the statements were present on the Makena website or in the brochure or prior to the time(s) they purchased Makena. The Complaint merely cites the current version of the website and the patient education brochure dated February 2019.

unlawfully." *Iqbal*, 556 U.S. at 678. "A claim is facially plausible 'when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Widmaier v. City of Newark*, No. 16-2533, 2019 WL 1895087, at *2 (D.N.J. Apr. 29, 2019) (Vazquez, J.) (quoting *Iqbal*, 556 U.S. at 678).

Claims that sound in fraud – like most of Plaintiffs' claims here – also must be pleaded with particularity under Rule 9(b). To satisfy this heightened pleading standard, a plaintiff "must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007). Here, Plaintiffs have not alleged sufficient facts to meet the requirements of Rule 8(a), let alone the heightened standard of Rule 9(b). The Complaint must be dismissed.

LEGAL ARGUMENT

I. PLAINTIFFS' CLAIMS ARE PREEMPTED BY FEDERAL LAW

The Supremacy Clause of the United States Constitution mandates that federal law is "Law of the Land, . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl.2. Thus, "state laws that conflict with federal law are without effect," and the United States Supreme Court "has found state law to be impliedly preempted where it is impossible for a private party to comply with both state and federal requirements." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 472-73, 480 (2013) (quotations omitted). Impossibility preemption exists where the private party could not "independently do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011). "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 623-

24. Neither is impossibility preemption avoided if the party may comply with both federal and state law by ceasing to act altogether. *Bartlett*, 570 U.S. at 488.

Plaintiffs' claims here attempt to challenge the FDA's determination that Makena is effective for its indicated use, and thus are impliedly preempted by federal law.

A. Plaintiffs Cannot Use State Law to Challenge the FDA's Approval of Makena

Each of Plaintiffs' claims stems from the same allegation: AMAG purportedly misrepresented Makena's effectiveness at reducing preterm births. (*See* Compl. ¶¶ 86, 93, 104, 114, 121, 130, 139 (consumer protection claims claim) ("AMAG misrepresented Makena's effectiveness"); *Id.* at ¶ 147 (unjust enrichment claim) ("[C]onsumers were misled . . . to believe that [Makena was] effective")). That argument, however, is in direct conflict with the FDA's determination at the time of Makena's approval that the drug ***is*** effective for that condition. (Ex. A, at 2 (stating that Makena is indicated for reducing "the risk of preterm birth" in certain women)); *see also* 21 U.S.C. § 355(d) (stating that FDA approval indicates there is "substantial evidence that the drug will have the effect it purports or is represented to have"); 21 C.F.R. § 314.105(b)-(c) (stating that the FDA will only approve a drug if the drug is effective).[11] Thus, what Plaintiff characterizes as misleading statements are in fact conclusions made by the FDA about Makena's effectiveness, and are thus accurate under federal law.

In essence, although Plaintiffs couch their claims in terms of representations about Makena's efficacy, their claims boil down to the contention that AMAG should not be selling Makena because, according to them (and notwithstanding the FDA's determination to the contrary), it is not effective at reducing preterm births. Courts have long rejected "stop-selling"

[11] To date, the FDA also has permitted Makena to remain on the market, even after the release of the PROLONG results. (*See* Compl. ¶¶ 63, 70) (acknowledging that the FDA is aware of the PROLONG results and has kept Makena on the market)).

or "never-start-selling" claims as preempted by federal law. *See, e.g.*, *Bartlett*, 570 U.S. at 488 (describing a "stop-selling" requirement as "incompatible with our preemption jurisprudence."); *In re Fosamax*, 751 F.3d at 164 n. 29 ("the stop-selling rationale was expressly rejected by the *Bartlett* Court as inconsistent with impossibility pre-emption jurisprudence"); *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 300 (6th Cir. 2015) ("We reject this never-start selling rationale for the same reasons the Supreme Court in *Bartlett* rejected the stop-selling rationale . . . ."); *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 677-78 (S.D.N.Y. 2017), *aff'd sub nom. Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699 (2d Cir. 2019) (dismissing claims challenging the FDA's safety and effectiveness determinations as preempted); *Brazil v. Janssen Research & Dev. LLC*, 196 F. Supp. 3d 1351, 1364 (N.D. Ga. 2016) (dismissing as preempted claim that manufacturer should never have sold drug); *cf. Batoh v. McNeil-PPC, Inc.*, 167 F. Supp. 3d 296, 322 (D. Conn. 2016) (dismissing as preempted claim that manufacturer should have redesigned drug); *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 246 n.8 (3d Cir. 2009), *aff'd sub nom. Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011) (design defect claim challenging efficacy preempted in light of "the FDA's far-more extensive control and oversight of the approval of a drug's design and alteration").

The case of *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228 (S.D. Fla. 2007), is particularly instructive. There, the plaintiffs alleged that Pfizer's advertisements for Lipitor were misleading because they portrayed the drug as effective for reducing heart disease, "even though there was not scientific evidence of such benefits." *Id.* at 1230-31. The court dismissed the claim (in relevant part) as preempted, stating:

> [T]he FDA approved Lipitor to reduce the risk of heart attacks in patients . . . . Its FDA approved label specifically includes this indication. Accordingly, any advertisements that stated or implied that Lipitor reduced the risk of heart disease or heart attacks simply marketed an approved use for the drug . . . . For this

> reason, the plaintiffs' efforts to hold Pfizer liable for the advertisements conflicts with the FDA's jurisdiction over drug labeling, and specifically its approval of Lipitor to reduce the risk of heart disease in some patients.

Id. at 1234-35. The same is true here: when approving Makena, the FDA determined that the drug was effective for its indicated use; Plaintiffs cannot challenge that approval – or AMAG's right to market Makena pursuant to and consistent with that approval – using state law. *See Id.*; *Utts*, 251 F. Supp. 3d at 677-78 (holding that claims challenging "a drug manufacturer's right to advertise FDA-approved drugs" are preempted).

B. Plaintiffs Cannot Use State Law to Challenge Marketing Statements Consistent with Makena's FDA-Approved Labeling

Nor can Plaintiffs use state law to challenge the specific statements from AMAG's marketing materials identified in the Complaint, because not only does that contention challenge the FDA's approval authority, but the statements are consistent with Makena's FDA-approved package insert. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 36, 43 (1st Cir. 2015) (noting that by approving a drug, the FDA makes a specific finding that the drug's labeling "is not false or misleading in any particular," and finding preempted claims based on efficacy statements contained therein) (citations omitted). In fact, Makena's accelerated approval requires AMAG to submit "promotional materials at least 30 days prior to the intended time of initial dissemination," allowing the FDA to comment on materials before they are used.[12]

Each of the purported misrepresentations[13] corresponds ***directly*** to a statement from the labeling:

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[12] 21 C.F.R. § 314.550

[13] The statement "Makena gives moms an extra layer of support," (Compl. ¶ 88(c)), relates to AMAG's patient assistance program for Makena, and there are no allegations of fact in the Complaint to suggest that it is false or misleading in any way. *See* note 8, *supra*.

Alleged Misrepresentation	Labeling Statement Approved by the FDA
• Makena . . . is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past. (Compl. ¶ 88(b)).	• Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. (Ex. A, at 2).
• Makena helps you get closer to term. (Compl. ¶ 88(a)). • Makena . . . helps give bab[ies] more time to develop. (Compl. ¶ 88(f)).	• The effectiveness of Makena is based on improvement in the proportion of women who delivered <37 weeks of gestation. (Ex. A, at 2).
• Receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy. (Compl. ¶ 88(d)). • Looking back, Makena gave me hope that I had a better chance of delivering Olivia full term. (Compl. ¶ 88(e)).	• Compared to controls, treatment with Makena reduced the proportion of women who delivered preterm at < 37 weeks. The proportions of women delivering at < 35 and < 32 weeks also were lower among women treated with Makena. (Ex. A, at 13).

Courts have held that claims challenging marketing materials that mirror FDA-approved labeling[14] are preempted because such a finding "would be fundamentally equivalent to finding that the FDA's approved labeling was false or deceptive." *Williams v. Bayer Corp.*, 541 S.W.3d 594, 602-03 (Mo. Ct. App. 2017) (dismissing as preempted consumer protection claims based on statements made on prescription device's promotional website); *see also Prohias*, 490 F. Supp.

[14] A drug's marketing materials must be consistent with its FDA-approved labeling. *See* 21 U.S.C § 352 (n); 21 C.F.R. §§ 202.1(e)(3), (5), (6); *In re Celexa*, 779 F.3d at 41 ("After approval, the manufacturer may distribute the drug without violating federal law as long as it uses the FDA-approved label.").

2d at 1234; *Mills v. Warner-Lambert Co.*, 581 F. Supp. 2d 772, 789-90 (E.D. Tex. 2008); *cf. In re Celexa*, 779 F.3d at 41; *Utts*, 251 F. Supp. 3d at 677-78.[15] The Court should do the same here.

II. PLAINTIFFS' CLAIMS LIE WITHIN THE PRIMARY JURISDICTION OF THE FDA AND ARE NOT PROPERLY REVIEWED BY THIS COURT.

The Complaint is also improper under the primary jurisdiction doctrine because it would require this Court to intrude on the FDA's purview as sole determiner of whether a prescription drug is safe and effective for its indicated use. The Court is empowered to dismiss the Complaint for this additional reason, or, in the alternative, to grant a stay while Plaintiffs file their grievance with the FDA.[16]

Under the primary jurisdiction doctrine, a court may dismiss (or stay pending administrative review) any claim that would require the court to resolve questions "within the special competence of an administrative agency." *Reiter v. Cooper*, 507 U.S. 258, 268 (1993). In determining whether dismissal or a stay is appropriate, courts in the Third Circuit (and elsewhere) consider four factors: "(1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise, (2) whether the question at issue is particularly within the agency's discretion, (3) whether there exists a substantial danger of inconsistent rulings, and (4) whether a prior application to the agency has been made." *Clark v. Actavis Grp. hf*, 567 F. Supp. 2d 711, 715 (D.N.J. 2008) (quotation omitted); *see also Bernhardt v. Pfizer, Inc.*, No. 00 CIV. 4042 LMM, 2000 WL 1738645, at *2 (S.D.N.Y. Nov. 22, 2000) (applying primary jurisdiction

[15] Some of these cases pertain to medical devices and not prescription drugs; however, "[t]he similarities between the approval process for medical devices and the approval process for drugs make the reasoning [from the medical devices] cases relevant here." *Mills*, 581 F. Supp. at 786 (dismissing consumer protection claim challenging marketing of effectiveness of approved OTC drug as preempted).

[16] FDA regulations provide a mechanism for the public to petition the FDA to take certain requested action. *See* 21 C.F.R. §§ 10.25, 10.30 (setting forth the procedure for filing a "citizen petition" to request that the FDA take or refrain from taking administrative action).

doctrine to stay claims seeking an injunction to require drug manufacturer to provide notice of post-market study results that purportedly demonstrated that the drug was less effective than an alternative treatment). Each of these factors weighs in favor of dismissal here.

First, and as discussed above, there is no question that Congress has entrusted the FDA with ***sole*** authority to determine the safety and effectiveness of prescription drugs, and that the Complaint's allegations directly challenge the FDA's prior conclusion, based on its review of the relevant clinical data, that Makena is effective to reduce the risk of preterm birth. Congress has charged the FDA explicitly with that task. *See* 21 U.S.C. § 355.

Second, the determination of whether clinical data supports a claim for efficacy indisputably involves "technical or policy considerations" and therefore is properly entrusted to the expert judgment of the FDA. Plaintiffs' claims would require this Court to delve into the clinical data in order to adjudicate whether the FDA properly interpreted that data in approving Makena for its indicated use. The FDA, not federal courts, has the scientific expertise to evaluate clinical findings, interpret their meaning, weigh them against each other, and determine whether they establish substantial evidence of efficacy. *See Tri-Bio Labs., Inc. v. U.S.*, 836 F.2d 135, 142 (3d Cir. 1987) ("We are mindful that in evaluating scientific evidence in the drug field, the FDA possesses an expertise entitled to respectful consideration by this court."); *Henley v. Food and Drug Admin.*, 77 F.3d 616, 621 (2d Cir. 1996) ("[T]he average consumer cannot be expected to analyze and weigh each conflicting study . . . . The FDA possesses the requisite know-how to conduct such analyses, by sifting through the scientific evidence to determine the most accurate and up-to-date information regarding a particular drug."); *Premo Pharm. Labs., Inc. v. United States*, 629 F.2d 795, 803 (2d Cir. 1980) ("[T]he FDA . . ., as distinguished from a court, possesses superior expertise, usually of a complex scientific nature.").

Third, deciding whether Makena is effective for its indicated use case ***clearly*** would create a "substantial danger of inconsistent rulings." The FDA has ***already determined*** that Makena is effective and that statements to that effect are not false or misleading.

Finally, application to the FDA has already been made with respect to certain issues relevant to this lawsuit, including Plaintiffs' contention that the PROLONG trial results undermine the FDA's determination that Makena is effective to reduce the risk of preterm birth. (*See* Compl. ¶¶ 63, 69-70).[17] Courts regularly stay lawsuits in such circumstances – indeed, invocation of primary jurisdiction is particularly appropriate "when the regulatory agency has actions pending before it which may influence the instant litigation." *TON Servs., Inc. v. Qwest Corp.*, 493 F.3d 1225, 1239 (10th Cir. 2007); *see also In re KIND LLC "Healthy & All Natural" Litig.*, 209 F. Supp. 3d 689, 696 (S.D.N.Y. 2016) (staying consumer protection class action over alleged misrepresentations that a product was "all natural" where the FDA was considering pending citizen petitions on that issue); *In re Gen. Mills, Inc. Kix Cereal Litig.*, Civ. No. 12-249 (KM), 2016 WL 5110499, at *1 (D.N.J. June 13, 2016) (ordering a stay of consumer protection action where pending FDA request for comments specifically covered the issue underlying the alleged misrepresentations); *Higgenbotham v. Diversified Consultants, Inc.*, No. 13-2624-JTM, 2014 WL 1930885, at *3 (D. Kan. May 14, 2014) (staying consumer protection lawsuit where pending FCC petition involved one of the issues underlying the plaintiffs' claims).[18]

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[17] *See, e.g., Acknowledgment Letter from FDA Docket Management Staff to Public Citizen* (Oct. 8, 2019), https://www.regulations.gov/document?D=FDA-2019-P-4683-0002 (noting that the FDA has docketed a citizen petition seeking withdrawal of approval for Makena); *Citizen Petition from Public Citizen* (Oct. 8, 2019), https://www.regulations.gov/document?D=FDA-2019-P-4683-0001 (seeking withdrawal of approval for Makena based on the PROLONG trial results).

[18] Even if the FDA were to withdraw approval of Makena in response to the pending citizen petition or otherwise, Plaintiffs' claims still would fail for the reasons addressed herein, among

Because the Complaint raises questions falling squarely within the FDA's primary jurisdiction – including questions the FDA has already reviewed and adjudicated and/or is in the process of adjudicating – dismissal or, if necessary, a stay pending FDA review of a citizen petition, is appropriate. *See, e.g.*, *In re Human Tissue Prods. Liab. Litig*., 488 F. Supp. 2d 430, 433 (D.N.J. 2007) (directing plaintiffs to file a citizen petition with the FDA); *Bernhardt*, 2000 WL 1738645, at *3 (applying primary jurisdiction doctrine and noting plaintiffs have option of filing citizen petition with the FDA); *Taradejna v. Gen. Mills, Inc.*, 909 F.Supp.2d 1128, 1135 (D. Minn. 2012) (dismissing consumer protection claims and directing parties to "initiate the proper proceedings with the FDA"); *Aaronson v. Vital Pharm., Inc.*, No. 09-CV-1333 W(CAB), 2010 WL 625337, at *2-3 (S.D. Cal. Feb. 17, 2010) (dismissing consumer protection claims because "more than the average consumer, [the FDA] knows how to weigh conflicting studies and determine the most accurate and up-to-date information regarding product safety"); *Tutoki v. Celebrezze*, 375 F.2d 105, 107 (7th Cir. 1967) (affirming dismissal of claim because the "district court has neither the facilities nor the expertise to pass on [that issue] in the first instance").

III. PLAINTIFFS' NEW YORK, NEW JERSEY AND CALIFORNIA CONSUMER PROTECTION CLAIMS ARE BARRED BY SAFE HARBORS

Three of Plaintiffs' consumer protection claims are expressly barred by statutory or precedential "safe harbors" that make clear that those statutes do not cover alleged misrepresentations regarding the sale of heavily regulated prescription drugs like Makena that are marketed in compliance with FDA requirements.

A. New York's Statutory Safe Harbor Bars Plaintiffs' GBL § 349(a) Claim

Count VI of the Complaint alleges that AMAG violated New York General Business Law ("GBL") § 349(a), which outlaws "[d]eceptive acts or practices in the conduct of any

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others – they have not sufficiently pled (and cannot plead) a claim that escapes preemption or states a plausible claim for relief under applicable state law.

business." (Compl. ¶¶ 126-131); N.Y. Gen. Bus. § 349(a) (2014). But GBL § 349(d), the statute's "safe harbor" provision, acts as a "complete defense" to any liability under GBL § 349(a) if an "act or practice is . . . subject to and complies with the rules and regulations of . . . any . . . agency of the United States." N.Y. Gen. Bus. § 349(d). Courts have applied the safe harbor provision when pharmaceutical manufacturers have marketed their drug in compliance with FDA requirements. *See In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, Civ. A. No. 11-5304, 08–08, 2013 WL 1558697, at *7 (D.N.J. Apr. 11, 2013) ("[c]ompliance with FDA warning requirements is a complete defense" to a GBL 349(a) claim) (citing *Am. Home Prod. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144 (S.D.N.Y. 1987).

Plaintiffs do not allege (nor can they) that any of the statements in question exceed or overstate the content of Makena's FDA-approved labeling. All of the alleged misleading statements pertain to Makena's efficacy at reducing preterm birth in certain women. (Compl. ¶ 132(a)-(f)). The FDA explicitly approved Makena for that indication. (Ex. A, at 2). AMAG therefore marketed Makena pursuant to this FDA-approved indication and in compliance with FDA requirements. The safe harbor provision bars Plaintiffs' GBL claim. *See In re Fosamax*, 2013 WL 1558697, at *8 ("Fosamax is approved by the FDA, and therefore, this approval is a complete defense to a § 349 claim"); *Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) ("[R]epresentations . . . that comport substantively with statements approved as accurate by the FDA cannot supply the basis for [GBL 349] claims."); *cf. Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 64 (2d Cir. 2016) ("[R]epresentations commensurate with information in an FDA label generally cannot form the basis for Lanham Act [false advertising] liability. ").

B. The New Jersey Consumer Fraud Act Does Not Apply to Sales of Prescription Drugs or Other Comprehensively Regulated Industries

Count I of the Complaint alleges that AMAG violated New Jersey Consumer Fraud Act ("NJCFA"). Although the NJCFA does not include an express statutory safe harbor like GBL § 349, New Jersey courts have declined to apply it to activities that are comprehensively regulated by federal or state agencies, like the direct-to-consumer marketing of prescription drugs. *See, e.g.*, *N.J. Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 177-78 (N.J. Super. Ct. App. Div. 2003). In *Schering*, plaintiffs brought consumer fraud claims against a pharmaceutical manufacturer in connection with its direct-to-consumer (DTC) sales strategy for its then-prescription Claritin products, on behalf of a nationwide class of Claritin users who were allegedly damaged by false claims about the efficacy of the product. *Id.* at 175-76. The Appellate Division affirmed dismissal, noting that "plaintiffs' complaint overlooks an essential difference between the pharmaceutical industry and others." *Id.* at 177. Specifically, the combination of the requirement of a physician's prescription and extensive regulation by the FDA undercuts the need for additional consumer protection. First, the court noted that "as a practical matter," prescription pharmaceutical products are different than most everyday products in that they are available ***only*** through a physician's prescription. *Id.* at 177. "[T]he intervention by a physician in the decision-making process necessitated by his or her exercise of judgment whether or not to prescribe a particular medication protects consumers in ways respecting efficacy that are lacking in advertising campaigns for other products." *Id.* at 177-78. Next, the court observed that "[r]egardless of the claims in the DTC advertising campaign, the products in question remain subject to the strict regulation of the FDA." *Id.* at 177 (citing 21 U.S.C. § 352; 21 C.F.R.§ 202.1). "In this context, that is, within a highly regulated industry in which the ultimate consumer is not in fact free to act on claims made in advertising in any event, the

relationship between words used in the advertising and purchase of the product is at best an attenuated one." *Id.* at 178.

Schering is consistent with longstanding New Jersey precedent holding that the NJCFA does not apply to advertisements in industries (like the pharmaceutical industry) that are comprehensively regulated by federal or state agencies. *See Daaleman v. Elizabethtown Gas Co.*, 390 A.2d 566, 568-70 (N.J. 1978) (holding that a privately owned public utility company could not be held liable under the NJCFA because it is within the exclusive jurisdiction of the public utility commission). As the New Jersey Supreme Court has explained:

> In order to overcome the presumption that the [NJ]CFA applies to a covered activity, a court must be satisfied, as this Court was in *Daaleman*, that a direct and unavoidable conflict exists between application of the [NJ]CFA and application of the other regulatory scheme or schemes. ***It must be convinced that the other source or sources of regulation deal specifically, concretely, and pervasively with the particular activity, implying a legislative intent not to subject parties to multiple regulations that, as applied, will work at cross-purposes***. We stress that the conflict must be patent and sharp, and must not simply constitute a mere possibility of incompatibility.

Lemelledo v. Benefit Mgmt. Corp., 696 A.2d 546, 554 (N.J. 1997) (emphasis added) (ultimately finding that the NJCFA applied to loan-packing activities because the court did not find sufficient conflict with relevant industry regulations); *see also Macedo v. Dello Russo*, 840 A.2d 238, 242 (2004) ("[A]dvertisements by learned professionals in respect of the rendering of professional services are insulated from the [NJ]CFA but subject to comprehensive regulation by the relevant regulatory bodies . . . ."). Here, Plaintiffs cannot meaningfully dispute that the FDA's regulations "deal specifically, concretely, and pervasively with the particular activit[ies]" alleged in the Complaint. Accordingly, Plaintiffs' NJCFA claim should be dismissed.

C. California's "Safe Harbor" Bars Plaintiffs' UCL & CLRA Claims

Like New York and New Jersey, California has adopted a "safe harbor" doctrine that bars claims under California's Unfair Competition Law ("UCL") and Consumer Legal Remedies Act

("CLRA") (Counts II and III) involving conduct otherwise permitted by law – in this case, FDA regulations applicable to the marketing of Makena for its approved indication. *See, e.g.*, *Alvarez v. Chevron Corp.*, 656 F.3d 925, 933 (9th Cir. 2011) (affirming dismissal of UCL and CLRA claims based on California safe harbor doctrine, when allegedly improper gasoline dispenser design had been certified by a California regulator); *Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 973 P.2d 527, 541 (Cal. 1999) ("If the Legislature has permitted certain conduct . . . courts may not override that determination. When specific legislation provides a 'safe harbor,' plaintiffs may not use the general unfair competition law to assault that harbor."). The alleged misstatements that underlie Plaintiffs' California claims are all related to Makena's efficacy for reducing preterm birth. (Compl. ¶¶ 95, 106). The FDA approved Makena specifically for ***that*** indication. (Ex. A, at 2). Makena's FDA-approved indication (and statements consistent with the FDA's approval) cannot be challenged through California's UCL and CLRA.

IV. THE LEARNED INTERMEDIARY DOCTRINE PRECLUDES PLAINTIFFS' CLAIMS

Although Plaintiffs frame their claims as consumer protection claims, they essentially complain that that AMAG failed to warn about Makena's allegedly limited efficacy and the results of the PROLONG trial. (*See* Compl. ¶ 30 ("[T]he data used to support Makena's [accelerated approval] application and subsequent approval, though, was insufficient to assess Makena's efficacy."); *Id.* at ¶ 64 ("AMAG knew far earlier than finalization of the PROLONG [trial] that Makena was ineffective."); *Id.*, *passim* (faulting AMAG for marketing Makena as effective despite the PROLONG results)). Such claims are not only preempted, they are also barred by the learned intermediary doctrine.

Each of the states at issue in this lawsuit recognizes the learned intermediary doctrine, which precludes claims based on an alleged failure to warn consumers where prescription drug

manufacturer has provided adequate warnings to physicians. The New Jersey Products Liability Act (NJPLA), N.J.S.A.§ 2A:58C-1, *et seq.*, for example, codifies the learned intermediary doctrine previously recognized by the Supreme Court of New Jersey, which held that "a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities." *Niemiera v. Schneider*, 555 A.2d 1112, 1117 (N.J. 1989) (internal citation omitted). *See also* N.J.S.A.§ 2A:58C-4. Courts in New York, California, Kansas, Missouri and Wisconsin recognize the same principle.[19] Under the learned intermediary doctrine, a prescription drug manufacturer satisfies its duty to warn by providing adequate warnings to physicians. *See Seavey v. Globus Medical Inc.*, Civ. No. 11-2240 (RBK/JS), 2014 WL 1876957, at *10 (D.N.J. Mar. 11, 2014) ("[A] drug or medical device manufacturer fulfills its duty to warn the ultimate user of its product when it provides a physician with an adequate warning . . . .").[20] And, "a presumption of adequacy attaches to a product's label warnings approved by the Food

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[19] *See DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 611 (S.D.N.Y. 2012) ("The New York Court of Appeals has adopted the Informed Intermediary Doctrine . . . which provides that a drug manufacturer's duty is to warn the treating physician, not the patient."); *Carlin v. Sup. Ct.*, 920 P.2d 1347, 1354 (Cal. 1996) ("[I]n the case of prescription drugs, the duty to warn runs *to the physician*, not to the patient.") (emphasis added); *Blain v. SmithKline Beecham Corp.*, No. 07-1157-MLB, 2008 WL 11381809, at *5 n.6 (D. Kan. Feb. 19, 2008) ("Kansas law [] provides that the manufacturer has a duty to warn the prescribing physician and not the patient"); *Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670, 671 (8th Cir. 1985) (applying Missouri law) ("[A] warning to the doctor is deemed a warning to the patient; the manufacturer need not communicate directly with all ultimate users of prescription drugs."). The Wisconsin Supreme Court has not directly addressed the applicability of the learned intermediary doctrine, but the Seventh Circuit has noted that "there is good reason to think that given the opportunity, the Wisconsin Supreme Court would join the vast majority of state supreme courts and adopt the learned-intermediary doctrine for use in defective-warning cases. . . ." *In re Zimmer, NexGen Knee Implant Prod. Liab. Litig.*, 884 F.3d 746, 751-52 (7th Cir. 2018) (citing cases applying the doctrine).

[20] *See also McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 402 (S.D.N.Y. 2014); *Samarah v. Danek Med., Inc.*, 70 F. Supp. 2d 1196, 1204 (D. Kan. 1999); *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 419-21 (Mo. Ct. App. 1999); *In re Zimmer*, 884 F.3d at 751.

and Drug Administration." *In re Accutane Litigation*, 194 A.3d 503, 524 (N.J. 2018); *see also* N.J.S.A. § 2A:58C-4.

Here, Makena's FDA-approved labeling provides detailed information about the drug's efficacy. The "Indications" section of the package insert provides that Makena is indicated to ***reduce the risk of*** preterm births, (Ex. A, at 2), not "***prevent***" them, as Plaintiffs incorrectly claim (Compl. ¶¶ 86, 93, 104, 114, 121, 130, 139). That section also states, "[w]hile there are many risk factors for preterm birth, safety and efficacy of Makena has been demonstrated only in women with a prior spontaneous singleton preterm birth. It is not intended for use in women with multiple gestations or other risk factors for preterm birth." (Ex. A, at 3 (emphasis in original)). And the "Clinical Studies" section adds, "[t]he upper bounds of the confidence intervals for treatment difference at < 35 and < 32 weeks were close to zero. Inclusion of zero in a confidence interval would indicate the treatment difference is not statistically significant." *Id.* at 13. Similarly, the labeling describes the Meis trial in detail, and expressly discusses the factors Plaintiffs identify in the Complaint as undermining the FDA's conclusions regarding Makena's efficacy. (*Compare* Ex. A, at 12-13 *with* Compl. ¶¶ 31-34).

In other words, Plaintiffs' prescribing physicians were adequately informed that (a) Makena reduces the risk of preterm births but may not outright prevent them, (b) other clinical risk factors could impact Makena's effectiveness, and (c) Makena's efficacy at certain points during pregnancy had limitations. Plaintiffs' prescribing physicians, as learned intermediaries, were in the best position to "balance the risks against the benefits" of Makena and make an informed decision about whether to prescribe Makena given Plaintiffs' individual circumstances. *See McDowell*, 58 F. Supp. 3d at 402 ("The prescriber, 'whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their

effects,' is thus the 'informed intermediary' between the manufacturer and the individual patient.") (citation omitted). Liability for any purported failure to warn Plaintiffs about Makena's efficacy rests with their prescribing physicians, not AMAG.[21]

Federal courts across the country have applied the learned intermediary doctrine to preclude consumer protection claims based on failure to warn at the motion-to-dismiss stage. *See, e.g., Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1372 (S.D. Fla. 2007) ("[F]ederal courts in jurisdictions across the country . . . have held that the learned intermediary doctrine encompasses all claims based upon a pharmaceutical manufacturer's failure to warn, including claims for fraud, misrepresentation, and violation of state consumer protection laws."); *Colacicco v. Apotex, Inc.*, 432 F.Supp.2d 514, 552 (E.D. Pa. 2006) *aff'd*, 521 F.3d 253 (3d Cir.2008) *cert. granted, judgment vacated on other grounds*, 556 U.S. 1101 (2009) (dismissing New York consumer protection claims as precluded by the learned intermediary doctrine); *Becker v. Cephalon, Inc.*, No. 14 CIV. 3864 NSR, 2015 WL 5472311, at *8 (S.D.N.Y. Sept. 15, 2015) (same); *Andren v. Alere, Inc.*, 207 F.Supp.3d 1133, 1144 (S.D. Cal. 2016) (dismissing UCL and CLRA action under California's learned intermediary doctrine). The Court should do the same here.

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[21] To the extent that Plaintiffs allege that AMAG failed to warn them about the PROLONG results, those claims are also barred by the learned intermediary doctrine. Plaintiffs' physicians bore the ultimate duty to stay abreast of the medical data on Makena and to warn patients about any efficacy concerns. *See Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1031 (D.N.J. 1988); *see also Ohuche v. Merck & Co.*, 903 F. Supp. 2d 143, 151 (S.D.N.Y. 2012) ("[I]t was Dr. Itzkovitz who should have read the available medical literature surrounding ZOSTAVAX® before she began vaccinating patients with it."); *Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 573 (D. Kan. 2006) (physicians are "presumed to have considerable medical training as well as the ability to access the medical literature if they require additional information"); *Humes v. Clinton*, 792 P.2d 1032, 1040 (Kan. 1990) (citation omitted) ("It is [the physician's] duty to inform himself of the qualities and characteristics of those products which he prescribes for . . . his patients . . . . The physician decides what facts should be told to the patient"); *Leibowitz v. Ortho Pharm. Corp.*, 307 A.3d 449, 457 (Pa. Sup. Ct. 1973) ("It is for the prescribing physician to use his own independent medical judgment, taking into account the data supplied to him from the drug manufacturer, other medical literature, and any other source available to him . . . whether to prescribe a given drug.").

V. PLAINTIFFS' FAIL TO PLEAD THEIR NEW JERSEY, CALIFORNIA, KANSAS, MISSOURI AND WISCONSIN CLAIMS WITH THE REQUISITE PARTICULARITY UNDER RULE 9(B)

The Federal Rules of Civil Procedure require claims grounded in fraud – like Plaintiffs' claims under the New Jersey NJCFA, California UCL and CLRA, Kansas Consumer Protection Act ("KCPA"), Missouri Merchandising Practices Act ("MMPA") and Wisconsin Deceptive Trade Practices Act ("WDTPA") – to be pleaded with particularity under Rule 9(b).[22] *See, e.g.*, *Frederico v. Home Depot*, 507 F.3d at 200 (noting that "[t]he stringent pleading restrictions of Rule 9(b)" apply to NJCFA claims).[23]

To satisfy this heightened pleading standard, a plaintiff "must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Lieberson v. Johnson & Johnson Consumer Cos.*, 865 F. Supp. 2d 529, 538 (D.N.J. 2011) (quoting *Frederico*, 507 F.3d at 200). "Indeed, the Third Circuit has advised that, at a minimum, a plaintiff must support allegations of fraud with all the essential factual background that would accompany 'the first paragraph of any newspaper story' – that is, the 'who, what, when, where and how' of the events at issue.'" *Id.* (quoting *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276-77 (3d Cir. 2006)); *see also Gonzalez*, 489 F. Supp. at 1247 (Rule 9(b) requires allegations of the "time, place and content of the alleged wrongful conduct, as well as the identities of the wrongdoers and the harm caused by plaintiffs'

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[22] Plaintiffs' GBL § 349 claims are examined under the more liberal pleading standard of Rule 8(a), *see Argabright v. Rheem Mfg. Co.*, 201 F. Supp. 3d 578, 607 (D.N.J. 2016), but as discussed in Section VI.A below, Plaintiffs fail to meet even that lenient standard.

[23] *See also In re Avandia Mktg., Sales, Practices & Prod. Liab. Litig.*, No. 07-MD-01871, 2013 WL 3486850, at *2 (E.D. Pa. July 10, 2013), *aff'd sub nom. In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 564 F. App'x 672 (3d Cir. 2014) (UCL and CLRA); *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125-27 (9th Cir. 2009) (same); *Gonzalez v. Pepsico, Inc.*, 489 F. Supp. 2d 1233, 1247 (D. Kan. 2007) (KCPA); *Blake v. Career Educ. Corp.*, No. 4:08CV00821 ERW, 2009 WL 140742, at *2 (E.D. Mo. Jan. 20, 2009) (MMPA); *Gelis v. Bayerische Motoren Werke Aktiengesellschaft*, No. 2:17-CV-07386, 2018 WL 6804506, at *7-8 (D.N.J. Oct. 30, 2018) (WDTPA).

reliance on any false representation."); *Blake*, 2009 WL 140742, at *3 (dismissing plaintiffs' MMPA claims for "fail[ure] to comply with the heightened pleading requirements of Rule 9(b)").

Plaintiffs in their Complaint identify a handful of purported misrepresentations that underlie their consumer protection claims. (Compl. ¶¶ 72-74). Noticeably absent from the Complaint, however, are any allegations as to ***when*** the alleged misrepresentations were made, ***what*** about them is fraudulent, and ***whether*** or ***how*** they caused any alleged harm. Plaintiffs cite the current version of the Makena website and a patient education brochure dated February 2019, but they do not allege that these representations were present on the website when Plaintiffs purchased Makena. Indeed, none of the Plaintiffs even allege that they saw the purported misrepresentations – much less explain how they relied on them in deciding to purchase Makena. In fact, they hardly describe their purchase of Makena, each alleging only that she was "prescribed, injected with, and purchased Makena" – an admission that a physician presumably issued the prescription and the drug was not specifically selected by her. (Compl. ¶¶ 2-13).

Courts in this district and elsewhere regularly dismiss consumer protection claims under New Jersey, California, Kansas, Missouri and Wisconsin law where plaintiffs fail to specify such details for failure to comply with Rule 9(b). *See, e.g.*, *Frederico*, 507 F.3d at 200 (dismissing NJCFA claims that did not allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation); *Butera v. Honeywell Int'l, Inc.*, No. 18-13417-SDW-LDW, 2020 WL 64568, at *7 (D.N.J. Jan. 6, 2020) (dismissing California UCL claim under Rule 9(b)); *Mattson v. Bristol-Myers Squibb Co.*, No. 07-908 (FLW), 2009 WL 5216966, at *9 (D.N.J. Dec. 30, 2009) (dismissing CLRA claim for alleged misrepresentations in Plavix advertisements because Plaintiff "fail[ed] to identify any specific advertisements she viewed, how she was misled by these advertisements, how these

advertisements affected her prescription for Plavix and how these advertisements caused any of her injuries.").[24] Dismissal is similarly warranted here.

VI. PLAINTIFFS FAIL TO ADEQUATELY PLEAD ESSENTIAL ELEMENTS OF THEIR CONSUMER PROTECTION CLAIMS

Putting aside Plaintiffs' failure to allege their claims with the particularity required by Rule 9(b), Plaintiffs fail to allege facts sufficient to render their claims plausible under the more lenient standard of Rule 8(a), *Iqbal* and *Twombly*. Although the elements of each statute differ, as a general matter Plaintiffs have failed to plausibly allege that any of the statements identified in the Complaint were misleading or deceptive or that Plaintiffs suffered any cognizable injury or ascertainable loss as a result of those statements (indeed, none of the Plaintiffs even allege to have read any of the statements at issue). AMAG will address each state-law claim in turn.

A. New York

To state a claim under GBL § 349 (the only one of Plaintiffs' consumer protection claims that is not subject to the heightened pleading requirements of Rule 9(b)), a plaintiff must plead: "(1) that the defendant's acts were consumer oriented, (2) that the acts or practices are deceptive or misleading in a material way, and (3) that the plaintiff has been injured as a result." *Spagnola*

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[24] *See also M.F. v. ADT, Inc.*, 357 F. Supp. 3d 1116, 1137 (D. Kan. 2018) (dismissing KCPA claim where, "[a]lthough Plaintiffs have pleaded with particularity the content of the statements, they have not sufficiently pleaded when the representation was made to Plaintiff."); *Jamieson v. Vatterott Educ. Ctr., Inc.*, 473 F. Supp. 2d 1153, 1157 (D. Kan. 2007) (same); *Craggs v. Fast Lane Car Wash & Lube, L.L.C.*, 402 F. Supp. 3d 605, 611 (W.D. Mo. 2019) (MMPA claim inadequately pled because, among other reasons, "Plaintiff has not alleged . . . when the representations were made"); *Khaliki v. Helzberg Diamond Shops, Inc.*, No. 4:11-CV-00010-NKL, 2011 WL 1326660, at *4 (W.D. Mo. Apr. 6, 2011) ("Absent from Plaintiff's allegations are specific details of the defendant's fraudulent acts, including when and where the acts occurred and who engaged in them."); *Blake v. Career Educ. Corp.*, No. 4:08CV00821 ERW, 2009 WL 140742, at *3 (E.D. Mo. Jan. 20, 2009) ("These allegations are extremely broad and notably fail to mention . . . the precise date on which each of the alleged fraudulent misrepresentations was made"); *Gelis*, 2018 WL 6804506, at *8 (dismissing WDTPA claims for lack of requisite particularity); *Moscinski v. Bristol-Myers Squibb Co.*, Civ. A. No. 06-6055 (FLW), 2009 WL 5216962, at *7-8 (D.N.J. Dec. 30, 2009) (same).

v. Chubb Corp., 574 F.3d 64, 74 (2d Cir. 2009) (affirming dismissal of GBL § 349 claim). Plaintiffs' claim fails at the second and third prong.

1. Plaintiffs Fail to Plausibly Allege any Misleading Statements

To state a claim under GBL § 349, a plaintiff must plausibly allege an act or statement that is "likely to mislead a reasonable consumer acting reasonably under the circumstances." *Cohen v. JP Morgan Chase & Co.*, 498 F.3d 111, 126 (2d Cir. 2007) (quotation omitted). Plaintiffs fail to do so here. As an initial matter, the statements identified in the Complaint are not misleading because, according to the FDA, they are accurate. *See* 21 U.S.C. § 355(d) (stating that FDA approval signifies that a drug is effective for its indicated use). Statements like "Makena helps you get closer to term" or "Makena . . . helps give bab[ies] more time to develop" correspond directly to Makena's indicated use of reducing the risk of preterm birth in certain women. (*Compare* Compl. ¶¶ 132(a), (b), (f) *with* Ex. A, at 2).

But even looking beyond the legal veracity of those statements, no reasonable consumer would interpret them as a universal guarantee of Makena's complete effectiveness. *See Schering*, 842 A.2d at 177 (finding that the phrase "you . . . can lead a normal nearly symptom-free life again" in a Claritin advertisement did not function as "a guarantee of universal and complete effectiveness"). The statements identified in the Complaint are exactly the type of "subjective claims of product quality" that have long been held non-actionable under GBL § 349. *Cytyc*, 12 F. Supp. 2d at 301 (general statements relating to efficacy of FDA-approved cancer screening product non-actionable under GBL § 349); *see also Leonard v. Abbott Labs., Inc.*, No. 10-CV-4676 ADS WDW, 2012 WL 764199, at *22 (E.D.N.Y. Mar. 5, 2012) ("General statements about compliance with safety and quality standards are non-actionable 'puffery.'"). A reasonable consumer viewing those statements understands what is prominently featured throughout the

Makena materials – "Your experience with Makena may vary." (Ex. D; *see also* Ex. E).[25] *See Hines v. Overstock.com, Inc.*, No. 09 CV 991 (SJ), 2013 WL 4495667, at *9-10 (E.D.N.Y. Aug. 19, 2013) (plaintiff "failed to plausibly plead her Section 349 claim" because the defendant's website fully disclosed the allegedly misleading practice of charging a return fee). These statements simply cannot support a GBL § 349 claim.

2. The New York Plaintiffs Fail to Plausibly Allege that the Purportedly Misleading Statements Caused Them any Injury

"To properly allege causation, a plaintiff must state in his complaint that he has seen the misleading statements of which he complains before he came into possession of the products he purchased." *Oden v. Bos. Sci. Corp.*, 330 F. Supp. 3d 877, 902 (E.D.N.Y. 2018) (dismissing GBL claim based on statements on medical device manufacturer's website and product brochure for failure to allege causation where "[n]one of the[ ] allegations provides any indication that Plaintiff ever saw these statements and, to the extent he did, where, when and how Plaintiff came to view either the website or the product brochure.") (quotation omitted); *Quintana v. B. Braun Med. Inc.*, No. 17-CV-06614 (ALC), 2018 WL 3559091, at *10 (S.D.N.Y. July 24, 2018) (same). When a plaintiff has not alleged to have seen the statements as issue, "they could not have been the cause of his injury." *Gale v. Int'l Bus. Mach. Corp.*, 9 A.D.3d 446, 447, (N.Y. App. Div. 2004) (dismissing GBL claim). The New York Plaintiffs here – Ms. Faughnan and Ms. Maltese – do not allege that they ever saw the statements on the Makena website or the patient education brochure, or that the statements otherwise functioned as the impetus for their

[25] As discussed in note 9, *supra*, the patient testimonial videos on the Makena website contain clear disclaimers. (*E.g.*, Ex. D). A similar disclaimer is included in the patient education brochure, a copy of which is attached as Exhibit E. *See Makena Patient Education Brochure*, Makena, https://makena.com/wp-content/uploads/2018/11/PP-MKN-US-00363-makena-auto-injector-patient-education-brochure.pdf, at 18 (last visited June 8, 2020) ("Please note that your results and duration of therapy may vary.").

purchase of Makena. Plaintiffs thus have failed to properly allege causation, and their claims should be dismissed.

B. New Jersey

"To state a New Jersey CFA claim, a plaintiff must plead with particularity: '(1) an unlawful practice; (2) an ascertainable loss on the part of the plaintiff; and (3) a causal relationship between the defendant's unlawful conduct and the plaintiff's ascertainable loss.'" *Grisafi v. Sony Elecs. Inc.*, Civ. A. No. 18-8494 (JMV)(JBC), 2019 WL 1930756, at *6 (D.N.J. Apr. 30, 2019) (Vazquez, J.) (dismissing NJCFA claim for failure to adequately plead any misrepresentation or omission); *Mehnert v. U.S. Bank Nat'l Ass'n*, Civ. A. No. 17-4985 (JMV), 2018 WL 1942523, at *7 (D.N.J. Apr. 23, 2018)) (Vasquez, J.) (same). "[T]o rise to the level of consumer fraud, the business practice in question must be misleading and stand outside the norm of reasonable business practice in that it will victimize the average consumer." *Id.* (quotation omitted). Plaintiffs cannot satisfy these elements.

1. Plaintiffs Fail to Allege "Unlawful" Conduct

Plaintiffs' consumer fraud claim fails because Plaintiffs' Complaint fails to allege that AMAG engaged in any unlawful conduct prohibited by the NJCFA. New Jersey courts have recognized three types of unlawful conduct: (1) affirmative misrepresentations; (2) omissions of material facts; and (3) violations of certain regulations promulgated under the statute.[26] *See Hassler v. Sovereign Bank*, 644 F. Supp. 2d 509, 514 (D.N.J. 2009), *aff'd*, 374 F. App'x 341 (3d Cir. 2010). The pleading requirements differ for claims based on affirmative misrepresentations versus those based on omissions – while affirmative misrepresentations will not require a showing of intent, omissions require that the defendant knowingly concealed material facts with the intention that the consumer rely upon the concealment. *See Judge v. Blackfin Yacht Corp.*,

[26] Plaintiffs do not allege any violation of those specific regulations.

815 A.2d 537, 542 (N.J. Super. Ct. App. Div. 2003); *Grisafi*, 2019 WL 1930756, at *6. In either case, "in recognition of the fact that the capacity to mislead . . . is the prime ingredient of all types of consumer fraud [under the CFA] . . . courts have dismissed CFA complaints for failure to state a claim where plaintiffs have failed to allege that the defendant engaged in conduct that could be considered misleading within the meaning of the Act." *Hassler*, 644 F. Supp. 2d at 514 (internal quotations and citations omitted).

Here, Plaintiffs contend that AMAG made affirmative misrepresentations regarding Makena's efficacy through a handful of statements on its website and in its patient education brochure. (Compl. ¶ 88). Plaintiffs also allege, albeit in conclusory fashion, that AMAG made unidentified "material omissions," presumably relating to the efficacy of Makena (although Plaintiffs do not specify). (Compl. ¶¶ 76-77, 87). None of these allegations are sufficient.

Plaintiffs' claim for affirmative misrepresentation fails because, as discussed in detail in Section VI.A.1 above: (1) the statements identified in the Complaint are not misleading because they are accurate according to the FDA; and (2) AMAG never guaranteed that Makena would prevent preterm births and no reasonable consumer would interpret them as such. *See, e.g.*, *Schering*, 842 A.2d at 177 ("The central contention of plaintiffs is that statements in DTC advertisements which used such phrases as 'you ... can lead a normal nearly symptom-free life again' were intended to be understood by consumers as a guarantee of total and universal effectiveness of the product. That contention is meritless.").

Plaintiffs' claim for omission fails because the Complaint does not allege – beyond conclusory statements – that AMAG knowingly concealed anything. While a defendant may be liable for failing to inform consumers of a known defect, courts in New Jersey have dismissed NJCFA claims for failure to allege facts sufficient to show knowledge and concealment, such as

"who at [defendant] possessed knowledge of the defect," "when or how the decision was made to conceal the defect from customers" and "that [defendant] knew that the [product] was certain to fail." *See Grisafi*, 2019 WL 1930756, at *6 (quoting *Glass v. BMW of N. Am., LLC*, No. 10-5259, 2011 WL 6887721, at *8 (D.N.J. Dec. 29, 2011)). The ***only*** allegation in the Complaint relating to AMAG's alleged knowledge of Makena's purported ineffectiveness states that, "[o]n information and belief, both because of the original problems with the Meiss [sic] study, and because the incoming data for the PROLONG trial were showing Makena was ineffective, AMAG knew far earlier than finalization of the PROLONG [trial] that Makena was ineffective." (Compl. ¶ 64). Plaintiffs' conclusory allegation based on "information and belief" is insufficient to support an omission claim. Plaintiffs do not allege when or how AMAG purportedly received "incoming data" from the PROLONG trial. The FDA itself determined that Makena is effective based on the results of the Meis trial, despite being fully aware of the alleged "original problems" Plaintiffs identify with the Meis trial and of the ongoing nature (at the time) of the PROLONG trial. (Compl. ¶¶ 32-34). Nor do Plaintiffs allege when AMAG purportedly knew that Makena was ineffective relative to when the Plaintiffs purchased or used Makena. These allegations are insufficient under Rule 8(a), let alone the heightened pleading standard of Rule 9(b). *See Grisafi*, 2019 WL 1930756, at *6.

2. Plaintiffs Fail to Plead Any Ascertainable Loss

Plaintiffs also have failed to sufficiently plead that they suffered an ascertainable loss, the second required element of an NJCFA claim. *See Hoffman v. Hampshire Labs, Inc.*, 963 A.2d 849, 854 (N.J. Super. Ct. App. Div. 2009) ("[A] plaintiff must present evidence that shows he suffered a quantifiable or otherwise measurable loss as a result of the alleged CFA unlawful practice.") (quotation omitted). Such a loss must be specifically pled to show "either an out-of-

pocket loss or a demonstration of loss in value[.]" *Solo v. Bed Bath & Beyond, Inc.*, Civ. No. 06-1908 (SRC), 2007 WL 1237825, at *3 (D.N.J. April 26, 2007).

Plaintiffs generically plead that they "suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiffs and New Jersey Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes." (Compl. ¶ 89). New Jersey Courts have repeatedly rejected this type of "fraud on the market" theory in the consumer fraud context.[27] For example, in *International Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co., Inc.*, plaintiff's "complaint allege[d] that defendant marketed its product as a safer and more effective alternative to other traditional pain medications, thus driving the price of its product substantially higher than the price charged for similar medications." 929 A.2d at 1079. The Supreme Court of New Jersey rejected this theory, stating: "to the extent that plaintiff seeks to prove only that the price charged for Vioxx was higher than it should have been as a result of defendant's fraudulent marketing campaign, and seeks thereby to be relieved of the usual requirements that plaintiff prove an ascertainable loss, the theory must fail." *Id.* at 1088; *see also Schering*, 842 A.2d at 179 (allowing a fraud on the market theory to satisfy the mandatory element of an ascertainable loss would "virtually eliminate the requirement that there be a connection between the misdeed complained of and the

[27] "Fraud on the market is essentially a creature of federal securities litigation. In that context, plaintiffs who purchased securities are permitted to demonstrate that they were damaged simply because defendant engaged in behavior otherwise prohibited and there was a change in price." *Int'l Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co., Inc.*, 929 A.2d 1076, 1087-88 (N.J. 2007) (citation omitted). "We have rejected the fraud on the market theory as being inappropriate in any context other than federal securities fraud litigation." *Id.* at 382 (citing *Kaufman v. i-Stat Corp.*, 165 N.J. 94, 97-98 (N.J. 2000)); *see also In re Ford Motor Co. E-350 Van Prods. Liab. Litig.*, Civ. No. 03-4558 (HAA), MDL 1687, 2008 WL 4126264, at *28 (D.N.J. Sept. 2, 2008) ("[T]o the extent Plaintiffs indeed allege their New Jersey CFA claim under a fraud on the market theory, this theory cannot survive.").

loss suffered [which would] . . . fundamentally alter the concept of causation in the CFA context."); *Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 381 n.7 (D.N.J. 2004) (same).

Courts likewise have rejected claims of ascertainable loss based solely on the purchase price where a plaintiff received the benefit of her bargain. *See Heindel*, 381 F. Supp. 2d at 380 (rejecting purchase-price-only claim where plaintiffs did not dispute that the drugs worked to relieve their pain). Here, neither New Jersey Plaintiff alleges that she gave birth pre-term. (Compl. ¶¶ 2-3). There is nothing in the Complaint to suggest they did not get what they paid for.

Plaintiffs also allege that they lost time undergoing "painful injections" (Compl. ¶ 90), but those injuries do not constitute "ascertainable loss of moneys or property" under the NJCFA. N.J.S.A. § 56:8-19. An ascertainable loss must be "quantifiable or otherwise measurable," *see Hoffman*, 963 A.2d at 854, and "encompass only economic losses." *Francis E. Parker Mem'l Home, Inc. v. Georgia-Pac. LLC*, 945 F. Supp. 2d 543, 552 (D.N.J. 2013); *see also Dabush v. Mercedes–Benz USA, LLC*, 874 A.2d 1110, 1116 (N.J. Super. Ct. App. Div. 2005) ("[A] private plaintiff must demonstrate an ascertainable loss of moneys or property, real or personal, as a result of the defendant's unlawful conduct.") (citations omitted). Allegations of lost time or pain and suffering do not suffice. *See Rapid Models & Prototypes, Inc. v. Innovated Sol.*, 71 F. Supp. 3d 492, 509 (D.N.J. 2014) (allegations of lost production time insufficient to plead an ascertainable loss); *Smith v. Trusted Universal Standards in Elec. Transactions, Inc.*, Civ. No. 09-4567 (RBK/KMW), 2011 WL 900096, at *14 (D.N.J. Mar. 15, 2011) (the "value of personal time" is not an ascertainable loss for purposes of the NJCFA); *Jones v. Sportelli*, 399 A.2d 1047, 1051 (N.J. Super. Ct. 1979) (damages for pain and suffering not recoverable under the NJCFA). Plaintiffs' failure to allege ascertainable loss dooms their NJCFA claim.

3. Plaintiffs Fail to Plead that Any Alleged Unlawful Conduct Proximately Caused Any Purported Loss

Finally, Plaintiffs cannot satisfy the final element of an NJCFA claim because there is no causal nexus between Plaintiffs' illusory injuries and AMAG's advertisements and marketing materials. *See Schering*, 842 A.2d at 176-77 (plaintiff must demonstrate "a causal relationship between the defendant's unlawful conduct and the Plaintiff's ascertainable loss."; *Cox v. Sears Roebuck & Co.*, 647 A.2d 454, 464-65 (N.J. 1994) (finding that the plaintiff could not demonstrate that consumer fraud occurred prior to any losses and denying damages stemming from these allegations). Plaintiffs do not allege that they ever saw AMAG's marketing materials prior to filling their prescriptions for Makena, or that the specific representations identified in the Complaint were even present on the website or in the patient education brochures when Plaintiffs purchased Makena. Those statements therefore cannot form the basis of viable NJCFA claims.

C. California

As with their New Jersey claims, Plaintiffs not only fail to meet the exacting standards of Rule 9(b) with respect to their California consumer protection claims under the UCL and CLRA, they cannot even meet the less stringent requirements of Rule 8(a).

1. Plaintiffs' CLRA Claims Fail

Plaintiffs' CLRA allegations fail to state a claim for three reasons. First, as discussed in Section VI.A.1, the statements upon which the CLRA claim is based are not misleading because they are an accurate summary of the drug's indication as approved by the FDA, and because they do not identify any "specific and measurable claim, capable of being proved false or of being reasonably interpreted as a statement of objective fact," and thus "cannot support a claim under the CLRA." *Rasmussen v. Apple, Inc.*, 27 F. Supp. 3d 1027, 1039-43 (N.D. Cal. 2014); *see also*

Consumer Advocates v. Echostar Satellite Corp., 8 Cal. Rptr. 3d 22, 29 & n.3 (Cal. Ct. App. 2003).

Second, to state a claim for violation of the CLRA, Plaintiffs must plausibly allege that they experienced damages "as a result of" the conduct at issue. Cal. Civ. Code § 1780(a); *see Meyer v. Sprint Spectrum L.P.*, 200 P.3d 295, 299 (Cal. 2009) ("The statute provides that in order to bring a CLRA action, not only must a consumer be exposed to an unlawful practice, but some kind of damage must result."). Unlike New York and New Jersey, California courts require allegations of ***actual reliance*** to state a claim under the CLRA. *See Sateriale v. R.J. Reynolds Tobacco Co.*, 697 F.3d 777, 794 (9th Cir. 2012) (affirming dismissal of CLRA claim because "consumers seeking to recover damages under the CLRA based on a fraud theory must prove actual reliance on the misrepresentation and harm") (citation omitted). Because of this reliance requirement, "[b]y definition, the CLRA does not apply to unfair or deceptive practices that occur ***after*** the sale . . . has occurred." *Moore v. Apple, Inc.*, 73 F.Supp.3d 1191, 1201 (N.D. Cal. 2014) (collecting cases).

Here, the Complaint does not expressly allege that Plaintiffs relied on any statements by AMAG. The only allegation that comes close consists of a single conclusory sentence stating that, but for AMAG's statements, Plaintiffs would not have purchased and been injected with Makena. (Compl. ¶ 76). Such conclusory statements are, on their face, inadequate. Plaintiffs do not allege that they ever saw the statements at issue – they do not even allege when the alleged misstatements were made or when they purchased Makena – and thus fail to plausibly allege that they relied on such statements before purchasing the product. On this basis alone, Plaintiffs' CLRA claim should be dismissed.

Plaintiffs' CLRA claim also suffers from a technical deficiency that warrants dismissal. California law required Plaintiffs to provide AMAG with written notice of the particular alleged violations of the CLRA "thirty days or more prior to the ***commencement***" of this action against AMAG. Cal. Civ. Code § 1782 (emphasis added). In order to "effectuate the clear intent of the act [which] is to provide and facilitate ***pre-complaint*** settlements of consumer actions wherever possible," the notice requirement is applied "literal[ly]" and "substantial compliance" is not sufficient. *Shein v. Canon U.S.A., Inc.*, No. CV-08-07323, 2009 WL 3109721, at *7 (C.D. Cal. Sept. 22, 2009) (quotation omitted). In this case, one of the four California Plaintiffs sent a CLRA notice to AMAG in a letter dated January 3, 2020—far fewer than 30 days prior to the January 13, 2020 commencement of the California action.[28] The other three California Plaintiffs never provided any pre-suit notice. Thus, the CLRA claims violate the statute's strictly construed notice requirements and should be dismissed on this basis. *See, e.g.*, *Mattson v. Bristol-Myers Squibb Co.*, No. 07-908-FLW, 2009 WL 5216966, at *7 (D.N.J. Dec. 30, 2009) (dismissing CLRA cause of action, in part, because Plaintiff did not "send a notice thirty days prior to ***filing*** her Amended Complaint which asserts a claim under the CLRA.") (emphasis added).

2. Plaintiffs' UCL Claims Fail

Plaintiffs' UCL allegations fail to state a claim for any practices that are unlawful, unfair, or fraudulent, *i.e.*, the three prongs of the UCL statute. *See, e.g.*, Cal. Bus. & Prof. Code § 17200; *Berryman v. Merit Prop. Mgmt. Inc.*, 62 Cal. Rptr. 3d 177, 185-87 (Cal. Ct. App. 2007). First, none of the conduct alleged by Plaintiff is unlawful. To be "unlawful" under the UCL, conduct must violate another law. *See, e.g.*, *Davis v. HSBC Bank Nevada, N.A.*, 691 F.3d 1152,

[28] *See Nelson v. AMAG Pharmaceuticals Inc.*, No. 2:20-cv-01975-JMV-SCM, Dkt. No. 1 (Jan. 13, 2020). A copy of the notice letter, dated January 3, 2020, is attached as Exhibit F.

1168 (9th Cir. 2012). Since Plaintiffs' CLRA claim fails and no other underlying violations are cited, Plaintiffs have not properly alleged any unlawful activity.

Second, Plaintiffs fail to properly allege conduct in violation of the UCL's "unfairness" prong. California courts are split between three tests to define "unfairness" in a consumer UCL suit, but Plaintiffs' allegations fail under any of these tests. *See, e.g., Clark v. Prudential Ins. Co. of Am.*, 736 F. Supp. 2d 902, 930 (D.N.J. 2010) (applying California law); *Davis v. Ford Motor Credit Co.*, 101 Cal. Rptr. 3d 697, 706-710 (Cal. Ct. App. 2009). The "tethering" test, originally applied to anti-competition (and not consumer) contexts, prohibits conduct that violates the "policy or spirit" of a "legislatively declared policy." *Clark*, 736 F.Supp.2d at 930 (citing *Cel-Tech*, 973 P.2d 527, 564-66 (Cal. 1999)). The marketing materials describing the FDA-approved indication for Makena are consistent with, rather than in violation of, FDA policy and thus cannot be unfair under this test. The "balancing" test defines an unfair business practice as one that is "immoral, unethical, oppressive or unscrupulous and causes injury to consumers which outweighs its benefits." *Clark*, 736 F. Supp. 2d at 930 (citing *McKell v. Wash. Mut., Inc.*, 49 Cal. Rptr. 3d 227, 240-41 (Cal. Ct. App. 2006)). It simply cannot be considered "immoral" or "unscrupulous" for AMAG to market Makena accurately and consistent with its FDA-approved indication. Other California courts apply a test requiring that the consumer injury is "substantial," that the injury is not outweighed by benefits to consumers, and that it is an "injury that consumers themselves could not reasonably have avoided." *Clark*, 736 F.Supp.2d at 930-31 (citing *Camacho v. Auto. Club of S. Cal.*, 48 Cal. Rptr. 3d 770, 777 (Cal. Ct. App. 2006)). Plaintiffs do not allege that the damage they experienced (apparently consisting only of the cost of Makena) was "substantial" or not reasonably avoidable. *See, e.g., Circle Click Media LLC v. Regus Mgmt. Group LLC*, No. 12-04000 SC, 2013 WL 57861, at *8 (N.D. Cal. 2013)

(dismissing UCL claim under unfairness prong because plaintiffs did not "explain[] why their alleged injury is substantial or why they could not have avoided the injury themselves.").

Third, Plaintiffs' allegations fail under the UCL's "fraud" prong for several reasons. As discussed above, AMAG's purportedly misleading statements are accurate and consistent with the FDA's approved indication for Makena and/or are not actionable assertions of fact for purposes of the UCL. *See, e.g., Anunziato v. eMachines, Inc.*, 402 F.Supp.2d 1133, 1140 (C.D. Cal. 2005) (statements regarding "quality," "reliability," and "performance" of a product are puffery not actionable under California's UCL). Thus, Plaintiffs fail to allege conduct by which "members of the public are likely to be deceived," a required element of a UCL fraud-prong claim. *Moran v. Prime Healthcare Mgmt. Inc.*, 208 Cal. Rptr. 3d 303, 317 (Cal. Ct. App. 2016) (citations omitted). Furthermore, like the CLRA, a UCL fraud-based claim requires allegations of "actual reliance" on the purported misstatements. *See, e.g., Mazza v. Am. Honda Motor Co., Inc.*, 666 F.3d 581, 596 (9th Cir. 2012) ("California courts have recognized that *Tobacco II* does not allow a consumer who was never exposed to an alleged false or misleading advertising campaign to recover damages under California's UCL.") (discussing *In re Tobacco II Cases*, 207 P.3d 20 (Cal. 2009)) (quotations omitted); *Kwikset Corp. v. Sup. Ct.*, 246 P.3d 877, 888 n.10 (Cal. 2011) ("[A] UCL fraud plaintiff must allege he or she was motivated to act or refrain from action based on the truth or falsity of a defendant's statement, not merely on the fact it was made."). Plaintiffs fail to plausibly allege actual reliance, thus their claims should be dismissed.

D. Kansas

The Complaint fails to plausibly allege essential elements of a KCPA claim.

1. Plaintiffs Fail to Plausibly Allege any "Deceptive" or "Unconscionable" Conduct or that AMAG Acted with the Requisite Knowledge or Intent

K.S.A. § 50-626(a) prohibits suppliers from engaging in "deceptive" acts. K.S.A. § 50-626(b) enumerates specific acts that are deemed deceptive. These acts all require a supplier to act with a certain mental state—"some of which require proof that the supplier made a representation the supplier knew or should have known was false and some of which require that the supplier engaged in willful conduct." *See Via Christi Reg'l Med. Ctr., Inc. v. Reed*, 314 P.3d 852, 865 (Kan. 2013). While Plaintiffs do not specify the subsection upon which their KCPA claim is based, (*see* Compl. ¶ 116), the Complaint is devoid of any facts illustrating (a) that the statements at issue were deceptive, or (b) that AMAG acted with the requisite intent.

As discussed above, the statements identified in the Complaint are not deceptive because, according to the FDA, they are accurate and because they are not the types of statements that are likely to mislead a reasonable consumer.[29] Nor does the Complaint include any non-conclusory allegations regarding AMAG's knowledge or intent. Plaintiffs allege only that, "[o]n information and belief, both because of the original problems with the Meiss [sic] study, and because the incoming data for the PROLONG trial were showing Makena was ineffective, AMAG knew far earlier than finalization of the PROLONG [trial] that Makena was ineffective." (Compl. ¶ 64). But Plaintiffs plead no ***facts*** supporting the basis for that belief. This is exactly the type of conclusory allegation that the Court must ignore when deciding whether Plaintiffs have plausibly pleaded their claims. *See Khalik v. United Air Lines*, 671 F.3d 1188, 1191 (10th

[29] Plaintiffs also reference K.S.A. § 50-627(a), which prohibits suppliers from engaging in "unconscionable" acts. (Compl. ¶ 116). The KCPA does not define unconscionability, but it does provide several "statutory examples of unconscionable acts." *State ex rel. Stovall v. DVM Enterprises, Inc.*, 62 P.3d 653, 656 (Kan. 2003). Those examples illustrate that there is no claim for unconscionability when there is no "evidence of any deceptive or oppressive practices, overreaching, intentional misstatements, or concealment of facts." *See State ex rel. Stovall v. ConfiMed.com, L.L.C.*, 38 P.3d 707, 714 (Kan. 2002). Such is the case here.

Cir. 2012); *Reedy v. Phillips 66 Co.*, No. H-17-2914, 2018 WL 1413087, at *10 (S.D. Tex. Mar. 20, 2018) (dismissing KCPA claim because, among other reasons, the plaintiffs did "not allege that Defendant acted willfully"); *cf. Tufts v. Newmar Corp.*, 53 F. Supp. 2d 1171, 1179 (D. Kan. 1999) ("It is not sufficient [for a KCPA claim] to allege that [defendant] willfully gave information that later proved to be false. To show willful conduct, plaintiffs must provide some indication that would allow a reasonable jury to conclude that [defendant]had a designed purpose to do wrong—i.e., that [defendant]intended to give the information even though [defendant] knew that it was false.").

2. Plaintiffs Fail to Plausibly Allege that Ms. Gill Has Been "Aggrieved" by Any Conduct by AMAG

"Under the KCPA, only aggrieved consumers may recover money damages." *Gonzalez*, 489 F. Supp. 2d at 1248 (citing K.S.A. § 50-634(a)-(b)). An "aggrieved consumer" is "one who suffers loss or injury as a result of a violation of the KCPA." *Id.* (citing *Finstad v. Washburn Univ.*, 845 P.2d 685, 691 (Kan. 1993)). Here, the only Kansas Plaintiff, Ms. Gill, has not plausibly alleged any injury caused by the alleged misrepresentations. She does not claim to have relied on the alleged misrepresentations when purchasing Makena – she does not even contend that she ever viewed the statements.

The Kansas Supreme Court's decision in *Finstad v. Washburn University* makes clear that this failure is fatal to Plaintiffs' claims. 845 P.2d 685 (Kan. 1993). In that case, students in Washburn University's paralegal program alleged a KCPA violation based on misrepresentations in the University's course catalog advertising the program as accredited, when in fact it was not. *Id.* at 687. In affirming summary judgment for the University, the Kansas Supreme Court clarified that the KCPA incorporates a causation requirement based on the requirement that a plaintiff bringing a private cause of action under the Act suffer some loss or injury "as a result of

the violation" of the Act. *Id.* at 691. Because the students did not rely on the false statement, they could not establish that they were "aggrieved" by a KCPA violation. *Id.* The court explained:

> [M]any, if not all, of the students were unaware of the statement. Many enrolled prior to the publication of the statement in the university catalogue. Nor is there any showing that any of the students suffered injury or loss as a result of the publication of the statement. The students enrolled and paid the tuition. By so doing, they were consumers under the KCPA; however, the Act requires more in that they must also be aggrieved by the violation.

Id. Since *Finstad*, federal courts have dismissed KCPA claims for failure to allege that the plaintiff ever viewed the purported misrepresentations underlying the claim. *See M.F.*, 357 F. Supp. 3d at 1138 (plaintiffs failed to plead that they were "aggrieved consumers" under the KCPA where they "alleged no facts to show that decedent was aware of the statements on the website"); *Weckhorst v. Kansas State Univ.*, 241 F. Supp. 3d 1154, 1178 (D. Kan. 2017), *aff'd sub nom. Farmer v. Kansas State Univ.*, 918 F.3d 1094 (10th Cir. 2019).

Even if Plaintiffs could allege that Ms. Gill viewed the purported misrepresentations prior to purchasing Makena and relied on those representations, she has not suffered any injury as a result. Ms. Gill's pregnancy lasted until the 37th week. (Compl. ¶ 8). That is consistent with the statements alleged in the Complaint and Makena's FDA-approved labeling and marketing materials. (*See* Ex. A, at 2 ("[t]he effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation."). Ms. Gill is not alleged to have suffered any physical or other injuries as a result of taking Makena; thus, she has not suffered any cognizable loss. *See Porter v. Merck & Co.*, No. 04-CV-586, 2005 WL 3719630, at *1 (Kan. Dist. Ct. Aug. 19, 2005) ("[P]laintiff . . . suffered no physical injury and received a drug that provided relief from her pain. Thus, she has no loss."). Her KCPA claim fails accordingly.

E. Missouri

To state an MMPA claim, a plaintiff must allege (with particularity, as discussed above) that "she (1) purchased merchandise from the defendant; (2) for personal, family, or household purposes; and (3) suffered an ascertainable loss of money or property; (4) as a result of defendant's use of one of the methods, acts or practices declared unlawful by the Act." *Kelly v. Cape Cod Potato Chip Co.*, 81 F. Supp. 3d 754, 757 (W.D. Mo. 2015) (citing Mo. Rev. Stat. § 407.025.1)). Plaintiffs' claim fails at the third and fourth prong – they have not plausibly alleged any unlawful acts or that any such acts caused them any injury.

1. Plaintiffs Fail to Allege Unlawful Conduct

Plaintiffs contend that AMAG's statements that Makena was effective constitutes "deception, fraud … false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact" in connection with the sale or advertisement of merchandise in violation of the MMPA. (Compl. ¶ 122). The representations identified in the Complaint are not false or deceptive for purposes of the MMPA because they are consistent with Makena's FDA-approved indication (as discussed in Section VI.A.1 above), and because general claims of product quality are not actionable. *See Kelly*, 81 F. Supp. 3d at 762 ("The Court agrees that the federally-compliant ingredient label on the back of the chips defeats Plaintiff's claims that the Chips' labeling constitutes an unlawful practice under the MMPA"); *Martin v. WM. Wrigley Jr. Co.*, No. 4:17-cv-00541-NKL, 2017 WL 4797530, at *3 (W.D. Mo. Oct. 23, 2017) (package labeling that complies with FDA regulations is not misleading and does not violate the MMPA). Where, as here, "a Court can conclude as a matter of law that members of the public are not likely to be deceived . . . dismissal is appropriate." *Wright v. Bath & Body Works Direct, Inc.*, No. 12-00099-CV-W-DW, 2012 WL 12088132, at *2 (W.D. Mo. Oct. 17, 2012) (dismissing MMPA claims and finding that the defendant's advertisements on product quality

were not actionable under the MMPA because they were "puffery"); *see also Martin*, 2017 WL 4797530, at *6.

2. Plaintiffs Fail to Allege that the Purportedly Misleading Statements Caused any Injury

"[T]he plain language of the MMPA demands a causal connection between the ascertainable loss and the unfair or deceptive merchandising practice." *See Owen v. Gen. Motors Corp.*, 533 F.3d 913, 922 (8th Cir. 2008) (citing Mo. Rev. Stat. § 407.025.1). An MMPA claim therefore fails for lack of causation where a plaintiff "did not see, read, or know about" the alleged misrepresentations. *McCall v. Monro Muffler Brake, Inc.*, No. 4:10CV269 JAR, 2013 WL 1282306, at *5 (E.D. Mo. Mar. 27, 2013); *see also Bradley v. Hertz Corp.*, No. 3:15-CV-652-NJR-RJD, 2019 WL 3975177, at *4 (S.D. Ill. Aug. 22, 2019) ("[Plaintiff] could not have suffered an ascertainable loss when she admits she has never—to this day—viewed the alleged misrepresentations on [defendant's] website."). Here, the only Missouri Plaintiff, Ms. Barnes, does not allege that she ever saw the statements on AMAG's website or in the patient education brochure, or that the statements otherwise functioned as the impetus for her purchase of Makena. Plaintiffs thus fail to plausibly allege causation, an essential element of their MMPA claim.

F. Wisconsin

Plaintiffs' WDTPA claim also fails for lack of actionable misrepresentations or plausible allegations of causation. To prevail on a WDTPA claim, a plaintiff must prove three elements: (1) with the intent to induce an obligation, the defendant made a representation to the public; (2) the representation was untrue, deceptive or misleading; (3) the representation caused the plaintiff a pecuniary loss. *Moscinski*, 2009 WL 5216962, at *7 (D.N.J. Dec. 30, 2009) (citing Wis. Stat. §§ 100.18(1), 11(b)(2)). The Wisconsin Supreme Court has further clarified that "[r]eliance is an aspect of the third element." *Novell v. Migliaccio*, 749 N.W.2d 544, 553 (Wis. 2008).

For the reasons discussed above, Plaintiffs have not pleaded facts to support the second or third element. They have not identified any statements other than those that track the FDA's approved labeling or are general statements of product quality or opinion. *See Tietsworth v. Harley-Davidson, Inc.*, 677 N.W.2d 233, 246 (dismissing WDTPA claim and noting that general statements of product quality are "commercial puffs" that are "exclude[ed] . . . from the scope of actionable misrepresentations). Nor have Plaintiffs alleged that they viewed or relied upon any of the purported misrepresentations. Courts in this district and elsewhere have dismissed WDTPA claims for "fail[ure] to identify which, if any, of the promotional or marketing materials were received, viewed or relied upon by Plaintiffs, and if they were, when these materials were viewed and how they were relied upon." *Moscinski*, 2009 WL 5216962, at *8; *see also T&M Farms v. CNH Indus. Am., LLC*, No. 19-C-0085, 2020 WL 1082768, at *10 (E.D. Wis. Mar. 5, 2020) ("The complaint alleges that the false statements were made in 'marketing brochures, press releases, statements on CNH's website, and form statements by CNH dealers.' However, the complaint does not allege that any person affiliated with either of the plaintiffs read any of these brochures or press releases, visited CNH's website, or heard any specific 'form statement.'") (citations omitted). Dismissal also is warranted here.

VII. PLAINTIFFS' UNJUST ENRICHMENT CLAIM FAILS

The Complaint asserts a single unjust enrichment claim on behalf of all Plaintiffs based on the same allegations that underlie the consumer protection claims – that AMAG unjustly retained a benefit conferred on it by Plaintiffs as a result of AMAG's purported misrepresentations regarding the efficacy of Makena. (Compl. ¶ 146-147). Plaintiffs' unjust enrichment claim is duplicative of its consumer protection claims and should be dismissed for that reason alone. *See RJR Mech., Inc. v. Vassallo*, No. 12-CV-1810, 2017 WL 1534192, at *7 (D.N.J. Apr. 27, 2017) ("[U]njust enrichment is not a catchall cause of action to be used when

others fail" and, importantly, it is "not available where it simply duplicates" another claim) (quotations omitted); *Pollard v. AEG Live, LLC*, No. Civ. A. No. 14-1155 (SRC), 2014 WL 4637017, at *7 (D.N.J. Sept. 16, 2014) (dismissing unjust enrichment claim that "appears to amount to an attempt to re-frame the misconduct and injury underlying her NJCFA claim"); *Hidalgo v. Johnson & Johnson Consumer Co., Inc.*, 148 F. Supp. 3d 285, 298 (S.D.N.Y. 2015) ("[T]he unjust enrichment claim—which is based on identical facts as the [consumer protection] claim—is dismissed with prejudice"); *Tommey v. Computer Scis. Corp.*, No. 11-CV-02214-EFM-GLR, 2013 WL 1000659, at *3 (D. Kan. Mar. 13, 2013) (dismissing an unjust enrichment claim as duplicative of another claim).

"Unjust enrichment is a quasi-contractual remedy," and "New Jersey law[30] does not recognize unjust enrichment as an independent tort cause of action." *Torres-Hernandez v. CVT Prepaid Sols., Inc.*, No. 3:08-CV-1057-FLW, 2008 WL 5381227, at *9 (D.N.J. Dec. 17, 2008) (citation omitted). Where, as here, a "plaintiff asserts an unjust enrichment cause of action along with [other] tort claims and there appear to be no allegations that the plaintiff expected or

[30] Courts in this district have applied New Jersey law in dismissing unjust enrichment claims in multi-state consumer class actions notwithstanding that the consumer protection claims are governed by the laws of each class's home state, on the ground that "unjust enrichment laws do not vary in any substantive manner from state to state" and thus do not present an actual conflict under the first step of New Jersey's "most significant relationship" choice-of-law test. *Snyder v. Farnam Companies, Inc.*, 792 F. Supp. 2d 712, 723 (D.N.J. 2011) (citing cases); *but see In re Lamictal Indirect Purchaser and Antitrust Consumer Litig.*, 172 F.Supp.3d 724, 741, 755-56 (D.N.J. 2016) (applying individual state laws in dismissing unjust enrichment claims, albeit without conducting a separate choice-of-law analysis with respect to those claims). If the Court were to determine that Plaintiffs' unjust enrichment claims are instead governed by the laws of their home states, Plaintiffs' claims still would fail under those states' laws for the same reasons set forth herein and, with respect to Plaintiffs' California claim, for the additional reason that California does not recognize unjust enrichment as an independent cause of action. *See Cheramie v. HBB, LLC*, 545 Fed. App'x 626, 628 (9th Cir. 2013) (noting that the "weight of authority" in California "indicates that '[u]njust enrichment is not a cause of action, just a restitution claim") (citation omitted); *In re Lamictal*, 172 F.Supp.3d at 755-56 (dismissing unjust enrichment claim because it is "not a recognized independent cause of action" in California).

anticipated remuneration from the defendant, the unjust enrichment claim should be dismissed." *Jurista v. Amerinox Processing, Inc.*, Civ. No.12-3825 (NLH/JS), 492 B.R. 707, 754 (D.N.J. 2013) (quotation omitted); *Mason v. Coca-Cola Co.*, No. 09–0220–NLH–JS, 2010 WL 2674445, at *7 (D.N.J. June 30, 2010) (dismissing unjust-enrichment claim because the allegations "appear[ed] to sound in tort and not in quasi-contract" and the plaintiffs never alleged any expectation of remuneration from the defendant).

Plaintiffs' unjust enrichment claim also fails because Plaintiffs do not (and cannot) allege that they purchased Makena directly from AMAG. Because a plaintiff must confer a benefit on the defendant to support an unjust enrichment claim, this element has been interpreted by New Jersey courts as a requirement that "the plaintiff allege a sufficiently direct relationship with the defendant to support the claim." *Nelson v. Xacta 3000 Inc.*, Civ. A. No. 08–5426 (MLC), 2009 WL 4119176, at *7 (D.N.J. Nov. 24, 2009) (citing *Maniscalco v. Brother Int'l Corp.*, 627 F.Supp.2d 494, 505–06 (D.N.J.2009)); *see also Cooper v. Samsung Elec Am., Inc..*, Civ. A. No. 07–3853 (JLL), 2008 WL 4513924, at *10 (D.N.J. Sept. 29, 2008) (dismissing an unjust enrichment claim where consumer's purchase was through a retailer, as there was no relationship conferring any direct benefit on the manufacturer). "When consumers purchase a product from a third party, they confer a benefit on that third party, not on the manufacturer." *Snyder v. Farnam Co., Inc.*, 792 F. Supp. 2d 712, 724 (D.N.J. 2011) (dismissing unjust enrichment claim where plaintiffs failed to allege that they purchased the products at issue directly from defendants); *see also Nelson*, 2009 WL 4119176, at *7; *In re Ford Motor Co. E–350 Van Prods. Liab. Litig. (No. II)*, Civ. A. No. 03–4558 (GEB), 2010 WL 2813788, at *33 (D.N.J. July 9, 2010).[31] Failure to

[31] One court in this district has allowed an unjust enrichment claim to proceed despite the fact that the plaintiff bought the product at issue from a third-party retailer. *See Stewart v. Beam Global Spirits & Wine, Inc.*, 877 F. Supp. 2d 192, 201 (D.N.J. 2012). However, "the vast

allege the identity of the actual seller of the product (as Plaintiffs fail to do here) also warrants dismissal. *See Pollard*, 2014 WL 4637017, at *7 (dismissing unjust enrichment claim for failure to allege a sufficiently direct relationship where the complaint "does not actually identify the seller of [the product plaintiff purchased]").

Finally, Plaintiffs' unjust enrichment claim fails for the same reasons as their consumer protection claims – they have failed to adequately allege any actionable misrepresentations that caused them to purchase Makena, and therefore cannot show that AMAG's alleged retention of any benefit is "unjust." *See, e.g.*, *Gaul v. Bayer Healthcare LLC*, Civ. A. No. 12-5110 (SRC), 2013 WL 12181778 (D.N.J. Feb. 11, 2013) (dismissing NJCFA and unjust enrichment claims because the complaint failed to properly allege that a product was falsely advertised); *Martin*, 2017 WL 4797530, at *6 ("[T]he Eclipse® . . . packaging is not misleading, . . . [t]herefore, Plaintiff fails to plausibly allege that [defendant's] retention of the purported benefit was unjust – a critical element of her unjust enrichment claim . . . ."); *cf. In re Bayer Phillips Colon Health Probiotics Sales Practices Litig.*, No. CV 11-03017, 2017 WL 1395483, at *14 & n.12 (D.N.J. Apr. 18, 2017) (Vazquez, J.) (granting summary judgment on unjust enrichment claim where plaintiffs failed to show that statements regarding effectiveness of dietary supplement were false or misleading).

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majority of courts in this district have come out the other way. Indeed, courts in this district—both before and after *Stewart*—have overwhelmingly held that a manufacturer cannot be held liable for unjust enrichment if the plaintiff purchased the product at issue from a third-party." *Noble v. Samsung Elecs. Am., Inc.*, Civ. A. No. 15-3713, 2018 WL 801590, at *7 & n.10 (D.N.J. Feb. 8, 2018) (citing nine cases from this district holding that an indirect purchaser cannot assert a claim for unjust enrichment).

CONCLUSION

For the foregoing reasons, Defendant AMAG respectfully requests that this Court grant its motion to dismiss Plaintiffs' Complaint in its entirety, with prejudice, for failure to state a claim upon which relief can be granted.

Respectfully submitted,
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